Office Action Summary	Application No.	Applicant(s)	
	10/577,637	BARRITAULT ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/17/09; 2/22/10*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/17/06, 5/11/07, 8/7/09*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20100222*.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of the polymer RGTAE-82 in table 2 and pain as the indication being treated in the reply filed on December 17, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

In the search for the elected species, prior art directed to non-elected embodiments was discovered. This discovery is not an indication that the full scope of the claims has been examined.

Comments and Notes

2. It is noted that claim 16 contains two different types of symbols, in which the "*" is used to indicated items which are part of a list which only relates "the pain and/or pruritus induced by". It is kindly suggested that those items that only relate to that item be further indented to reduce any potential confusion that might arise, such as an assumption that the different symbols were typographical errors.

Specification

3. The disclosure is objected to because of the following informalities: abbreviations are used in the specification without being spelled out so it is unclear what these abbreviations stand for and as they are not common art recognized abbreviations, such as DMF is known in the art to be dimethylformamide. "CMD" and "FA" are used in example 1 and it is unclear what these abbreviations stand for.

Appropriate correction is required.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1 – 9, 12, 14 and 16 are provisionally rejected on the ground of nonstatutory obviousness-type as being unpatentable over claims 2 - 6 of U.S. Patent No. 6,689,741. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US'741 recite the administration a polymer of the same formula as required by the instant claims to tissues such as the skin (cutaneous cicatrisation, claim 3), the cornea (claim 4) or bone (claims 5 and 6). The claims of US'741 recite a polymer with the formula AaXxYy, wherein A is a monomer, X is a -R-COO-R' wherein R is a bond and R' is a hydrogen atom or cation; Y is a –R-O-SO_3-R' or –R-N-SO_3-R' wherein R is a bond and R' is a hydrogen atom or a cation, x is the substitution rate of the monomers A by group X, which is comprised of approximately 20% and 150%; and y is the substitution rate of monomers A by group Y

which is comprised of approximately 30 and 150%. Such polymers are the same polymers which are contacted with a tissue in the tissue. As the same active step is occurring in the claims of the instant application and US'741, the same results must necessarily occur, whether the result is facilitating cicatriazation as in the claims of US'741 or treating or preventing discomfort, unpleasant symptoms, irritation or pain associated with a tissue as in the instant claims.

6. Claims 1 – 9, 12, 14 and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 70 of copending Application No. 10/695574. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 -9, 12, 14 and 16 are generic to all that is recited in claim 10 of US Application 10/695574. That is, claim Y 10 of US'574 falls entirely within the scope of claims 1 – 9, 12, 14 and 16 or, in other words, claims 1 – 9, 12, 14 and 16 are anticipated by claim 10 of US'574 . Specifically, the claims of US'574 recite a polymer of formula AaXxYy, wherein A is a glucose monomer; X is $-CH_2COOH$ or $-CH_2COO^-Na^+$; Y is a $-SO_3^-$; Z is phenylalanine or tyrosine; x is the substitution rate of the monomers A by group X, which is comprised of approximately 20% and 150%; y is the substitution rate of monomers A by group Y which is comprised of approximately 30% and 150% and z is substitution rate of monomers A by group Z. Phenylalanine and tyrosine are Z groups capable of providing the functionalities recited in claims 7 and 9 of the instant application. These polymers are administered for the treatment of fibroses, which requires contacting a tissue with a

composition containing the biocompatible polymers. As the same active step is occurring, the same results must necessarily occur, whether the result is treating fibroses as in the claims of US'574 or treating or preventing discomfort, unpleasant symptoms, irritation or pain associated with a tissue as in the instant claims.

This is a provisional obviousness-type double patenting rejection.

7. Claims 1 – 9, 12, 14 and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 12/212093. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same active step is recited in the claims of the two applications with compositions comprising the same biocompatible polymers. The claims of US'093 recite the administration of a therapeutically effective amount of a polymer of formula AaXxYy, in which A is a sugar or O-CH2-CH2-CO- group; X is –R-COOR' wherein R is the same as in the instant claims and Y is sulfate or sulphonate group of formula R-O-SO_3R' or R-N-SO_3-R' wherein R is a bond; x is the substitution rate of the monomers A by group X, which is comprised of approximately 20% and 150%; and y is the substitution rate of monomers A by group Y which is comprised of approximately 30% and 150%. These polymers are administered for the treatment of fibroses, which requires contacting a tissue with a composition containing the biocompatible polymers. As the same active step is occurring, the same results must necessarily occur, whether the result is treating

fibroses as in the claims of US'093 or treating or preventing discomfort, unpleasant symptoms, irritation or pain associated with a tissue as in the instant claims.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112 1st Paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1 – 9, 12, 14 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The application as originally filed required that the Y substituent have an O or N-sulphonate group bound to A with an aliphatic hydrocarbon chain, possibly branched and/or unsaturated and which may contain one or more aromatic rings, connecting A and the sulphonate group. The amendment to the claims alter the connectivity of these atoms and to requires the O or N-sulphonate group to be attached to the monomer A without any intervening groups. The particular polymers that were synthesized using the procedure set forth in example 1, which do not have any intervening groups, do meet the written description provision. However, those examples are limited to glucose

monomers and O-sulphonate addition using a sulfur trioxide reaction and are insufficient to support a generic formula (I) of AaXxYy in which the O- or N-sulphonate group of Y is directly attached to A without an intervening R group for all monomers A.

10. Claims 7 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. Claims 7 and 9 relate to an optional substituent Z in the biocompatible polymer which can bestow additional biological, physical or chemical properties such as improved solubility or lipophilicity. The examples provided in the specification for Z are amino acids, fatty acids, fatty alcohols, ceramides and nucleotide addressing sequences (¶ [0026] of the instant specification). Due the wide variety of polymer properties which may be altered, the wide variety of structures disclosed as being able to alter these properties and the lack of known structure-function relationship in the art, only those Z groups which were explicitly mentioned in the specification meet the written description provision. Due to the breadth and diversity of the genus encompassed by the functional language of the instant claims, these species are insufficient to provide written description support for the full breadth of the genus recited in claims 7 and 9.

11. Claims 1 – 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating or pain associated with a tissue, does not reasonably provide enablement for treating or preventing all discomfort, unpleasant symptoms and irritation and preventing pain associated with a tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The disclosure and claims of the application have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) as to undue experimentation

The factors include:

1. The nature of the invention;
2. The breadth of the claims;
3. The predictability or unpredictability of the art;
4. The amount of direction or guidance presented;
5. The presence or absence of working examples
6. The quantity of experimentation necessary;
7. The state of the prior art; and
8. The relative skill of those skilled in the art.

Each factor is address below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

1. The nature of the invention; the breadth of the claims: that claims are drawn to a method in which a tissue is contacted with a therapeutically effective amount of a biocompatible formula with the general formula AaXxYy as defined in claim 1. This is a very broad formula as A can be any monomer. The method is intended to treat or prevent discomfort, unpleasant symptoms, irritation or pain associated with a tissue.

2. The amount of direction or guidance presented, the presence or absence of working examples: a large numbers of examples of the treatment of pain associated with various conditions are presented in the specification (examples 1 – 24), such as arthritis (example 21), discomfort and pain related to bronchial obstruction (example 14) and skin lesions caused by radiotherapy (example 9). No indication is given if all of the polymers of the invention were investigated to treat pain associated with each of these causes. The polymers were also contacted after the pain began and so give no indication that they can prevent pain. No examples are presented in which unpleasant symptoms associated with a tissue, such as skin darkening caused by the sun, wrinkles, infections of wounds or sores, were presented. The examples also indicate that the pain associated with respiratory allergy phenomena (hay fever, cat or rat hair allergy) was alleviated but not that other discomfort or unpleasant symptoms associated with respiratory allergy phenomena, such as sneezing, watery eyes or congestion were alleviated.

3. The quantity of experimentation necessary, the state of the prior art, and the relative skill of those skilled in the art: While the relative skill of those skilled in the art is high, the instant application has demonstrated the treatment of pain from a wide variety of causes. However, evidence regarding the treatment or prevention of discomfort, unpleasant symptoms or irritation unrelated to pain has not been set forth. As discussed above, the terms discomfort, unpleasant symptoms or irritation associated with a tissue can have causes other than pain and the instant application does not indicate that all such discomfort, unpleasant symptoms or irritation can be treated or prevented by contacting the tissue with the polymers according to the instant invention. Therefore, the full scope of the claims is not enabled.

Claim Rejections - 35 USC § 112 2nd Paragraph

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1 – 9, 12, 14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The structure of the biocompatible polymer is unclear. Formula (I) indicates that A is attached to X and in turn X is attached to Y. Repeating units are generally indicated by square brackets with possible substituents of the monomer. Therefore, it is unclear what structural

arrangements are required for the resulting polymers as the formula (I) does not allow Y to be attached to A but to X.

"R" is defined as being "an aliphatic chain...which may contain one or more aromatic rings" but as defined in the art, an aliphatic chain does not contain any aromatic rings.

It is also unclear what "x" and "y" represent as the claims are drawn to products, not a process for making the product, and thus there are no rates involved to be a "rate of substitution". The basis upon which the percentages of these rates of substituted is calculate, as in claims 4, 5 and 8, is unclear as no baseline rate has been described.

Please clarify.

14. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. "A" is a monomer, but claim 2 states that the monomer may be nucleic acids or proteins, which are polymers, not monomers. Please clarify.

15. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim contains the limitation "greater than approximately 2000 daltons". "Greater than" is a minima and all possible values above 2,000 Daltons are encompassed. "About" indicates a range centered on the recited value. In this case,

values both above and below 2000 Daltons. Therefore, what values are included in the range "greater than about 2000 daltons" cannot be determined.

16. Claims 12, 14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of these claims provides an intended use for pharmaceutical or dermatological composition or medical device that is used in the method of claim 1. It is unclear if these are the indications from which a patient must be suffering and that are subsequently treated or if that is only the intended use of the composition or medical device and not a limitation in the method of treating or preventing discomfort, unpleasant symptoms, irritation or pain associated with a tissue. Please clarify.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1 – 9, 12, 14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Barritault et al. (US 2001/0021758).

Barritault et al. discloses polymers of formula AaXxYy in which A is a glucose, a sugar monomer, on which X, Y and optional substituent Z are grafted on the hydroxyl functions of the glucose monomer (¶ [0187]). X is $-CH_2COOH$ or $-CH_2COO^-Na^+$, which reads on the X substituent of the instant claims (¶ [0188]). Y is $-OSO_3H$ or $SO_3^-Na^+$, which reads on the O-sulphonate Y substituent of the instant claims (¶ [01890]). Such polymers with different degrees of carboxylmethylation and sulphonation falling within the ranges of the instant claims are set forth in the table of figure 6. The invention pertains to the pharmaceutical compositions of the polymers which are contacted with tissue (¶ [0126]). The carboxymethyl dextran sulfate polymers RGTA 1005 and 1012 are contacted with rat tissue in example 8 (¶¶ [0317]).

The instant claims recite contacting a tissue with a composition comprising a biocompatible polymer as defined by claim 1. Barritault et al. discloses contacting a tissue with a composition comprising a biocompatible polymer as defined by claim 1. Therefore, Barritault et al. must disclose a method of treating or preventing a discomfort, unpleasant symptom, irritation or pain associated with a tissue as both the cited prior art and the instant claims recite contacting a tissue with a composition comprising a biocompatible polymer as defined by claim 1.

In regard to claims 7 and 8, the cited polymers, z has a value of 0, i.e., there is no Z substituent present in the polymer.

In regards to claims 12, 14 and 16, the various indications are the intended use of the pharmaceutical or dermatological composition or the medical device. A recitation of the intended use of the claimed invention must result in a structural difference

between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As polymers of the same structure as taught by Bartritualt et al. are recited by the instant claims, which are capable of being used to treat pain, the polymers in the cited prior art are capable of performing the intended uses recited in claims 12, 14 and 16.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claims 1 – 9, 12, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barritault et al. (US 6,689,741) as evidenced by Hunter et al. (US 2003/157161)

Barritault et al. discloses polymers of formula AaXxYy, wherein A is a monomer, X is a -R-COO-R' wherein R is a bond and R' is a hydrogen atom or cation; Y is a –R-O-SO_3-R' or –R-N-SO_3-R' wherein R is a bond and R' is a hydrogen atom or a cation, x is the substitution rate of the monomers A by group X, which is comprised of approximately 20% and 150%; and y is the substitution rate of monomers A by group Y which is comprised of approximately 30% and 150% (¶¶ [0039] – [0046]). Specific polymers in which A is a glucose monomer on which X, Y and optional substituent Z are grafted on the hydroxyl functions of the glucose monomer (¶ [0187]) are also disclosed. X is $–CH_2COOH$ or $–CH_2COO^-Na^+$, which reads on the X substituent of the instant claims (¶ [0188]). Y is $–OSO_3H$ or $SO_3^-Na^+$, which reads on the O-sulphonate Y substituent of the instant claims (¶ [01890]). Such polymers with different degrees of carboxylmethylation and sulphonation are set forth in the table of figure 6. The invention

pertains to the pharmaceutical compositions of the polymers which are contacted with tissue (¶ [0126]). The carboxymethyl dextran sulfate polymers RGTA 1005 and 1012 are contacted with rat tissue in example 8 (¶¶ [0317] – [0319]). The polymers may be substituted with various groups Z such as those which are capable of conferring supplementary biological or physicochemical properties, such as better solubility or lipophilic properties enabling better diffusion or tissue penetration, increasing amphiphilic properties, such as amino acids, fatty acids, fatty alcohols, ceramides or nucleotide addressing sequences (p [0057]). z, the substitution rate of the A monomers with groups Z are comprised between approximately 0 an 50%, preferably on the order of 30% (¶ [0059]).

Barritault et al. does not explciitly provide an example of the treatment of pain.

Barritault et al. discloses that the compositions containing the polymer can be used as therapy for the inflammation of arthritis (col 11, ln 38). Hunter et al. provides evidence that pain is among the symptoms of inflammatory arthritis (¶ [0103]) so the treatment of arthritis is a method of treating pain.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to contact an inflamed, arthritic tissue with a polymer according to Barritault et al. for the purposes of treating pain. The person of ordinary skill in the art would have been motivated make those modifications and reasonably would have expected success because Barritault et al. discloses that the polymers can be used as therapy for the inflammation of arthritis (col 11, ln 38). Hunter et al. provides evidence that pain is among the symptoms of inflammatory arthritis (¶ [0103]) so the treatment of

arthritis encompasses a method of treating pain. Additional evidence to this point can be found in instant claim16, which indicates that pain and/or pruritus can be induced by arthritis.

In regard to claims 7 and 8, the cited polymers have a z has a value of 0%, i.e., there are no Z substituents present in the polymer.

23. Claims 1 – 9, 12, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barritault et al. as evidenced by Hunter et al. as applied to claims 1 – 9, 12, 14 and 16 above, and further in view of Deibig et al. (US 4,451,452).

As discussed in greater detail above, Barritault et al. as evidenced by Hunter et al. discloses polymers according to formula (I) which are contacted with tissues for the treatment of conditions such as arthritis, which includes treating discomfort, unpleasant symptoms, irritation or pain associated with a tissue. The polymers may be substituted with various groups Z such as which are capable of conferring supplementary biological or physicochemical properties, such as better solubility or lipophilic properties enabling better diffusion or tissue penetration, increasing amphiphilic properties, such as amino acids, fatty acids, fatty alcohols, ceramides or nucleotide addressing sequences (p [0057]). z, the substitution rate of the A monomers with groups Z are comprised between approximately 0 an 50%, preferably on the order of 30% (¶ [0059]).

Barritault et al. does not disclose polymers substituted with acetate groups as Z.

Deibig et al. discloses the modification of the physical properties of water-soluble polymers such as dextran by incomplete esterification with mono- or di-carboxylic acid

that make the polymers water-insoluble but still water-swellable (abstract). The selection of the polymeric hydroxy compound, the acylating group and the degree of acylation enables a wide range of polymers of different properties and hydrolysis rates to be prepared (col 1, ln 27 – 20). In example 4, dextran acetate is prepared (col 5, ln 19 – 43). As shown in table I (col 6), increasing the degree of substitution of a larger carboxylic acid side chain, butyrate, on dextran, decreased the amount of water uptake (swellability) of the polymer.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to substitute the carboxymethylated and O-sulphonated biocompatible polymers of Barritault et al. with acetate groups. The person of ordinary skill in the art would have been motivated to make those modifications to alter the swellability and solubility properties of the resulting polymers and reasonably would have expected success because Deibig disclose that substitution of dextran with carboxylic acids such as acetate affects the physical properties of the final polymers, allowing for polymers with a wide variety of final characteristics based on the identity and degree of substitution of the polymer.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW